OCT 2 6 2009

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K091696

1. Submitter's Identification:

Medicomp, Inc.
7845 Ellis Road
Melbourne, Florida 32904

Date Summary Prepared: May 8, 2009

Contact: Mr. Michael Thomas

2. Name of the Device:

SAVI Wireless Model PM500

3. Predicate Device Information:

K#043454, CardioPAL SAVI (Model PM410) Event/Loop Recorder, Medicomp, Inc.

4. Device Description:

The SAVI Wireless Model PM500, is a small, auto triggered, hand-held device, prescribed by physicians for patients who are experiencing symptoms that may be attributable to cardiac arrhythmia. Shortness of breath and palpitations are examples of these symptoms. This device may be worn for a period of days or weeks – whatever time is necessary to capture and record the ECG.

The device consists of the SAVI Wireless event monitor, patient cable, and off the shelf cellular telephone. The device can be used with accessories, including a belt clip, lanyard, and PC interface cable.

5. Intended Use:

The SAVI Wireless Model PM500, is a pager-sized, hand-held or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as it is intended for use by patients

who are experiencing symptoms that are transient and infrequent in nature. Since the SAVI Wireless is patient-activated, the device is not intended for patients who are unable to activate the Record switch when they are experiencing a symptom.

6. Comparison to Predicate Device:

The following comparison chart outlines similarities and differences between the subject device and the predicate device:

Features	Predicate Device CardioPAL SAVI (PM410)	Subject Device SAVI Wireless (PM500)
ECG Storage	20 Minutes	20 Minutes
On Board Analysis	Yes	Yes
ECG Input	1 Channel 2 Wires 1 Channel 3 Wires 2 Channel 3 Wires 2 Channel 5 Wires	1 Channel 2 Wires 1 Channel 3 Wires 2 Channel 3 Wires 2 Channel 5 Wires
User Interface	Audio Beeper 2 Line x 16 Character LCD 3 Buttons	Audio Beeper 2 Buttons Cellular Telephone
PC Interface	Trans-telephonic USB	Cellular Network Bluetooth USB
Case	Plastic	Plastic
EC38 Type	Type 3	Type 3
Battery	1 AA	1 AA 1Rechargeable

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

All testing performed on the SAVI Wireless was derived from the risk assessment which evaluated the effects of the feature changes. Testing included IEC 60601-1, IEC 60601-1-2, and environmental and software validation testing.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device, SAVI Wireless Model PM500, has identical indications for use as the predicate device, CardioPAL SAVI Model PM410. The bench testing

contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the SAVI Wireless Model PM500, is substantially equivalent to the predicate device, the CardioPAL SAVI Model PM410.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 2 6 2009

Medicomp, Inc.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants Inc
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K091696
Trade/Device Name: SAVI Wireless Model PM500
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: September 30, 2009
Received: October 1, 2009

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K091696

Device Name: SAVI Wireless Model PM500

Indications For Use:

The SAVI Wireless PM500, is a pager-sized, handheld or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.

Prescription Use _X_ **(Per 21 CFR 801 Subpart D)**	**OR**	**Over-The Counter Use_____** **(21 CFT 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091696